Author's response to reviews

Title: Economic evaluation alongside a single RCT of an integrative psychotherapeutic nursing home programme

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Author’s response to reviews: see over
JULY 22th, 2013

Dear Mrs. Calumpita and Professor Jon Karnon,

We revised our earlier submitted manuscript: “Economic evaluation alongside a single RCT of an integrative psychotherapeutic nursing home programme” (title revised)

(Trial registration nr.: ISRCTN 38916563)

We hope to have addressed all the your questions/suggestions in your mail of December 10th.

The specific modifications are described in the rebuttal on the comments/suggestions of the reviewer

In addition, we hope to have revised the manuscript fully in line with the requirements of your journal.

We look forward to receive a positive reaction Yours sincerely,

Dr. Ton Bakker, corresponding author

Reviewer’s report

Title: “Economic evaluation of an integrative psychotherapeutic nursing home programme; a randomised trial”

Version: 5 Date: 24 September 2012
Reviewer: Miranda Mugford

Reviewer's report:

Reviewer:
1. Is the question posed by the authors well defined? The paper presents an analysis of the economic data collected in a randomised trial of alternative forms of care for people with psychogeriatric symptoms, in terms of incremental cost per QALY gained over the period of the trial (about 6 months?) and in terms of the cost effectiveness of achieving key outcomes of the trial.

Our response:

The observation period of the trial in terms of incremental cost per QALY gained and in terms of the cost effectiveness of key outcomes has been more accurately described in the section Design of the manuscript.

Reviewer:
The economic question is not really spelled out: it is important that readers understand this, perhaps with the aid of a decision tree. Was the trial designed with a specific economic question in mind?

*Our response:*

*We fully agree that the economic question is not really spelled out. We are the reviewer very grateful for her critical comment.*

*The performed RCT was designed to test the (cost-)effectiveness of IRR to reduce MPS in psychogeriatric patients who suffer from cognitive impairment or dementia. We conducted a cost effectiveness study from a societal perspective, taking into account all relevant costs and effects. We extended the introduction section to explain the added value of an economic question and how this information may support decision makers confronted with budget constraints.*

*But, we do not really understand that a decision tree may be helpful. We expect that the modified Introduction sufficient is to understand our research question.*

Reviewer:

I am not sure how far the authors searched for previous economic evaluations of interventions in psychiatric care. The statement in the introduction that there has never been a previous trial should be modified: it may well be true, but might be better to say that the authors have not found such a trial in their searches.

*Our response:*

*We have adapted the text in the Introduction section conform reviewers comment.*

Reviewer:

2. Are the methods appropriate and well described? The details of the trial are summarised and presented in detail elsewhere. I found the summary very hard to follow, especially in the section 2.3 and figure 1.

*Our response:*

*We have changed the summary of the intervention in Section 2.3. as well as Figure 1.*

Reviewer:

The method for the economic evaluation is more or less acceptable as an analysis of data alongside a single RCT. Analysis of uncertainty is restricted to confidence intervals in costs and outcomes, and testing effects of missing data on results (I don't think this should be called 'robustness' which is a rather general term, but 'sensitivity to missing data'). There is no modelling of the probability of cost-effectiveness against different decision thresholds.

It is not clear whether the costs of the intervention are captured in the cost data collection instrument.
It is not clear what 'reference unit prices' are (section 2.4 page 6).

Our response:
We highly appreciate reviewer’s suggestion. The term ‘robustness’ will be modified fully according to the reviewer’s suggestion.

The following sentences were inserted in section 2.4. Costs were estimated by multiplying the use of health care by their corresponding unit prices. The number of days admitted to the nursing home was collected directly from the participating centres. The TrimebosiMTA for Costs \( (T_{iC-P}) \) was applied to collect data on all other use of health care from the patients. The \( T_{iC-P} \) measures medical resource utilisation by asking the number of contacts over the preceding last four weeks with different (medical and psychological) health care providers e.g. general practitioner, psychiatrist, medical specialist, physiotherapist. Unit prices for the interventions were estimated based on information of the financial department of Argos Zorggroep. Therefore, data on the direct (e.g. medical staff, nursing staff) and indirect costs (e.g. overhead, housing) of 2004 was used to calculate the unit costs per day for both interventions, respectively IRR and UC. All other health care utilisation was valued by their corresponding unit prices based on the Dutch manual for costing studies in Economic Evaluations. Unit prices of health care services for 2004 were adjusted to prices of 2005 by using the consumer price index (www.cbs.nl).

We have more specifically formulated the phrases about ‘reference unit prices’.

In addition, CEAC-analyses have been performed on QALYs and NPI-severity scores.

Reviewer:

3. Are the data sound?

Yes, as far as I can judge from what is presented. The reported costs and EQ5D scores seem feasible.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?

This is not primarily the report of an RCT, and although in many ways it does adhere to the guidelines such as CONSORT, with a flowchart of patients, it also misses many key issues such as method of randomisation and degree of masking of the results from analysts (it is reported that this is not a blinded trial for caregivers and participants and data collectors)

Our response:

Admittedly, in our manuscript we have not fully described our adherence to the CONSORT guidelines. However, to our belief, we have adhered to the CONSORT guidelines as much as feasible in geriatric practice. The degree of masking was limited. As the intervention condition (IRR: Integrated Rehabilitation and Reactivation Programme) implied that the patients were admitted to the psycho-geriatric nursing
home, and as the condition comprised patients who underwent routine treatment (UC: Usual nursing home Care), it was not feasible to blind for participants and their caregivers, as well as for data collectors.

The method of randomization as well as the degree of blinding are added in the Design section 2.2.

Reviewer:
The reporting of a cost effectiveness study could be improved to follow, for example, the York Centre for Reviews and Dissemination NHSEED guidance or the BMJ checklist.

Our response:
We improved the presentation of the economic evaluation according to Drummond’s checklist for assessing economic evaluations.

Reviewer:
5. Are the discussion and conclusions well balanced and adequately supported by the data?
Mainly acceptable.

6. Are limitations of the work clearly stated? Yes. It is particularly relevant that the perspective of the CUA study (medical costs and patients' utility valuation) is highlighted, as this is an important controversy in the field of policy and economic evaluation of elderly care.

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
The paper is well referenced, but it is not clear how far the authors searched for related work.
See comment above about search for economic studies in this field – even if not done in the 'nursing home sector' I know of several economic evaluations of interventions for psychogeriatric patients which are included in the NHSEED database.

Our response:
We have reviewed the literature about cost and cost effectiveness studies in psychogeriatric field. Up to now, we did not find relevant literature about (cost-)effectiveness analysis in the field of psychogeriatrics.

Reviewer:
8. Do the title and abstract accurately convey what has been found? I think it could be reworded to make clearer that this is not the report of the RCT.
Our response:
We have changed the title according to your suggestion.
Also, we have reworded the abstract to make it more clear that it is not the report of an RCT, however an report of an economic evaluation.

Reviewer:
9. Is the writing acceptable?
Mainly it is clear, but in several places is difficult to read and could be rephrased. Sometimes sentences are incomplete. I have listed corrections below, but I also recommend a thorough proof read for clear English grammar

Our response:
We frankly acknowledge that a thorough proof read for clear English grammar is desired. Consequently, a native speaker / writer for professional translation into English has thoroughly screened and corrected (if it applied) the manuscript. The professional reader has been mentioned in the Acknowledgement section, according to the suggestion of the editor.

Reviewer:
• Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore)
1. Revise title:
2. Add decision tree(s) for the economic question(s Our response:
We have revised the title of the manuscript (see manuscript).
See our response on reviewers comment number 1.

Reviewer:
3. Clarify if the patient was present at 'multidisciplinary patient meetings' where GAS score was agreed.

Our response:
The patient was not present at 'multidisciplinary patient meetings' where GAS score was agreed.

Reviewer:
• Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Our response:
We have executed the minor essential revisions such as missing labels and wrong use of a term
1. Rewrite section 2.3 and figure 1 to make clearer the process and uptake of the intervention clearer. A flowchart might help, and it is not, in my view, necessary to repeat all the percentages in the text and the figure. (unless it is required journal style!)

Our response:
We have added a modified version of figure 1, and we rewrote section 2.3. Hopefully, it has become more clear.

Reviewer:
2. Spell out all acronyms. Mostly OK but what are DSM and MMSE?
3. Explain reference unit prices (page 6)
4. Correct references to Tables in section 3.2 should be 3 and 4, not 4 and 5
5. Several examples of unclear phrases or sentences include: a. page 3 line 9 'due to their multiplicity in combination' b. page 7 section 3.2 line 'the cost effectiveness in ICER'
c. page 8 last line. 'Completing of the EQ5D ...' this is not a sentence
d. page 9 line 5 from end: 'This means that the result of the economic evaluation were probably an underestimation of IRR' Do you mean an underestimation of the cost effectiveness of IRR?

Our response:
We have fully executed the foregoing suggestions c.q. Corrections

Reviewer:
• Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)
1. Clarification of the economic question(s) behind the study. Also spell out where and by whom and for what the 30,000 euro threshold is 'generally assumed' to apply (page 8)

Our response:
See our response on reviewers comment number 2; see also the changes in the Discussion section.

The economic questions behind the study have been clarified. Furthermore, where and by whom and for what the 30,000 euro threshold is generally assumed.

Reviewer:
2. More reference in intro and discussion to results and quality of previous economic evaluations in the field of psychogeriatric care
3. Be clear about whether intervention costs are included in the TiC-P – describe this
In this section, we will describe the methods. In particular, we will explain how the intervention was implemented and measured.

4. If you think a blinded trial is impossible, then why recommend that there should be blinded trials. You need to modify this recommendation.

Our response:

No references in introduction and discussion to results were found in the literature; and no literature about the quality of previous economic evaluations in the field of psychogeriatrics could be found.

The intervention costs were included in the TIC-P, and this instrument has been more fully described in the section Methods.

We have modified the phrase about blinded trials in the Conclusion section.

Reviewer:

Level of interest: An article of importance in its field
Quality of written English: Needs some language corrections before being Published

Our response:

As stated before, we frankly acknowledge that a thorough proof read for clear English grammar is desired. Consequently, a native speaker / writer for professional translation into English has thoroughly screened and corrected the manuscript.

Reviewer:

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.